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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/914,667 | 08/31/2001 | Stephen John Clifford Taylor | GJE-247 | 9973 |

109 7590 10/23/2003

THE DOW CHEMICAL COMPANY
INTELLECTUAL PROPERTY SECTION
P. O. BOX 1967
MIDLAND, MI 48641-1967

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| EXAMINER |
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LILLING, HERBERT J

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| ART UNIT | PAPER NUMBER |
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1651

DATE MAILED: 10/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/914,667

Applicant(s)

TAYLOR ET AL.

Examiner

HERBERT J LILLING

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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1. Receipt is acknowledged of the response filed September 11, 2003.

2. Claims 1-4 and 6-10 remain in this application.

Claims 5 and 11-18 were previously cancelled by the amendment of December 5, 2002.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 1-4 and 6-10 **stand** rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention with respect to the deposited strain in view of the following requirements to be in full compliance with the Rules of Deposits for U.S. Patent Applications:

It is apparent that the strain is required to practice the claimed invention(s) as recited in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the strain which is required to make and practice the instant invention to obtain the biocatalyst. See 37 C. F. R. 1.802.

The specification does not provide a repeatable method for obtaining the strain and it does not appear to be a readily available material. Deposit of the strain would satisfy the enablement requirements of 35 U.S.C. 112. If a deposit has been made, Applicant is required to meet the necessary criteria of the deposit rules in accordance with 37 CFR 1.801-37 CFR 1.809, **see below for the availability requirement.**

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If a deposit has not been supplied or made under the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature,

stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent would satisfy the deposit requirements, See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

b) all restrictions imposed by the depositor on the availability to the public of the deposited material **will be irrevocably removed** upon the granting of a patent;

c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification, See 37 CFR 1.803-37 CFR 1.809 for additional explanations of these requirements.

Applicant is kindly requested to be in compliance with the following:

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“A statement on the record by client or attorney for the availability as indicated above would be sufficient to overcome this rejection for the claimed inventions.”

Furthermore, if Applicant intends to claim the product microorganism of claim 16, now abandoned, in a divisional or CIP application, Applicant must include the identifying information as indicated above as set forth in 37 CFR 1.809(d) should be added to the specification. This information would be required for that claim but for the process of using the microorganism, one would be able to practice the instant application by obtaining an appropriate deposit.

B. Claims 1-4 and 6-10 stand rejected under 35 U.S.C. 112, first paragraph, as **failing to comply with the written description requirement**. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, **had possession of the claimed invention with respect to the “lactamase enzyme”**.

The specification lacks adequate written description for the claimed inventions in view of the following points in accordance with the written description requirements of 35 U.S.C. 112:

The claims are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the microorganism, does not reasonably provide enablement for the enzyme per se. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification according to **In re Fisher**, 427 F. 2d 833, 839, 166 USPQ 18, 24 (CCPA 1970): Section 112 requires that the scope of the claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of the enablement varies inversely with degree of unpredictability of the factors involved.

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The description must clearly allow persons of ordinary skill in the art to make and practice the instant An adequate written description of the claimed enzymes requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it however the specification has no evidence on the record that any enzyme was isolated but only a microorganism or cells of a microorganism has been employed as the biocatalyst.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re

Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) Accordingly, naming a type of material which may exist, in the absence of knowledge as to what that material consists of, is not a description of that material absent an indication that Applicants have isolated the enzyme per se.

Thus, the claims are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The broad generic claim lacks sufficient description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing since the specification lacks sufficient evidence of obtaining any enzyme that can be described by complete structure or identifying characteristics, thus the description requirement has not been satisfied.

The claims are not commensurate in scope with the enabling disclosure. Examiner will accept language along the following line of reasoning:

Claim 1. Amend line 3:

---a microorganism from the genus *Rhodococcus globerulus* having a lactamase enzyme capableClaim 2 cancel

Claim 3, ----wherein the *Rhodococcus globerulus* is in the form a cell paste or intact cells.

Claim 4-ok

Claim 5 was cancelled as noted above in the amendment of Dec 5, 2002.

Claim 6 ok

Claim 7 ok

Claim 8 ok

Claim 9 ok

Claim 10 cancel.

The arguments have been deemed not to be persuasive that Applicant has support for the claimed language commensurate in scope with the enabling written description.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 10 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant has not furnished the indicated copies of the deposited strains. The arguments have been found to be persuasive upon a showing that the depository name has been changed for the second deposit for the NCIM41042. A submission of a copy the catalogue no. For NCIM41042, as being the *Rhodococcus globerulus* would be sufficient for the correct name as submitted on page 3. Otherwise, the claim as drawn to *Rhodococcus globerulus* strain identified, as CMC103381 would be not sufficient for support in the specification for the claimed species.

In addition, Applicant is required to change the name in the specification in accordance with proper name change with the support on the record for this change.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 6-10 are rejected under 35 U.S.C. 102(b) as anticipated by Reference F4, WO 92/18477 or, in the alternative, under 35 U.S.C. 103(a) as obvious over Reference F4, WO 92/18477

The reference teaches the resolution of beta lactams which are within the scope of the claimed members, see Ia and Ib, by employing a microorganism to hydrolyze one of the two enantiomers to form the acid and recover the unreacted enantiomer. If there are any differences with respect to the lactams, these differences would have been prima facie obvious in view of the broad disclosure of the reference.

The arguments have been found not to be persuasive for the claimed processes since the reference(s) are considered to be within the scope of the claimed subject matter.

The argued alleged limitations are not present in the claims.

6. **No claim is allowed.**

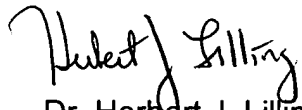
7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Examiner Lilling whose telephone number is (703) 308-2034** and **Fax Number** is for applications **Before Final** (703) 872-9306 and **After Final** for applications is 703-872-9307 or SPE Michael Wityshyn whose telephone number is (703) 308-4743. Examiner can be reached Monday-Thursday from about 5:30 A.M. to about 3:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

H.J.Lilling: HJL
(703) 308-2034
Art Unit 1651
October 22, 2003


Dr. Herbert J. Lilling
Primary Examiner
Group 1600 Art Unit 1651